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10/567,681	10/27/2006	Naofumi Mukaida	358275.20016	2886

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PATTON BOGGS, LLP
8484 WESTPARK DR.
9TH FLOOR
MCLEAN, VA 22102

EXAMINER	
LEAVITT, MARIA GOMEZ	
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1633	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,681	MUKAIDA ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *38-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 38-43, drawn to a **polypeptide and compositions** comprising the amino acid sequence of SEQ ID NO:1 and homologous sequences.

II. Claim 44 drawn to **a method for production of antibodies** specific to a polypeptide comprising the amino acid sequence of SEQ ID NO: 1

III. Claims 45 and 46 drawn to **antibodies** which specifically bind the amino acid sequence of SEQ ID NO:1

IV. Claim 47 drawn to **a Kit** comprising one or more antibodies elicited against the amino acid sequence of SEQ ID NO:1 and homologous sequences.

V. Claims 48-58, drawn to a **polynucleotide**, a vector comprising a polynucleotide, and host cells transformed with the vector**,** said polynucleotide encoding the amino acid sequence comprising the amino acid sequence of SEQ ID NO:1, homologous sequences, a sequence of SEQ ID NO: 2 including a nucleotide sequence form positions 436-1413 of SEQ ID NO. 2.

VI. Claim 59, drawn **to a method for the production of a polypeptide** having at least 80% homology to the amino acid sequence of SEQ ID NO: 1 comprising culturing a host cell transformed with a vector comprising a polynucleotide under a condition capable of producing the polypeptide.

VII. Claims 60-61, drawn **a PCR primer** comprising at least 15 nucleotides corresponding to a polynucleotide coding for a polypeptide comprising the amino acid sequence of SEQ ID NO: 1.

VIII. Claim 62 drawn to **a method for detecting a polynucleotide** comprising using a PCR primer comprising at least 15 nucleotides corresponding to a polynucleotide coding for a polypeptide comprising the amino acid sequence of SEQ ID NO: 1.

IX. Claim 63 drawn to **a Kit** comprising **PCR primers** comprising at least 15 nucleotides corresponding to a polynucleotide coding for a polypeptide comprising the amino acid sequence of SEQ ID NO: 1.

X. Claims 64-74 drawn to an **RNA molecule** and a pharmaceutical composition comprising 15 to 25 nucleotide pairs, comprising a nucleotide sequence corresponding to a partial sequence of a nucleotide sequence from positions 436 to 1413 of SEQ ID NO: 2.

XI. Claim 75 and 76 drawn to **a method for the production of a knockout cell** and the knockout cell comprising introducing an RNA molecule into a cell expressing a protein specific to human liver cancer said RNA molecule comprising 15 to 25 nucleotide pairs, comprising a nucleotide sequence corresponding to a partial sequence of a nucleotide sequence from positions 436 to 1413 of SEQ ID NO: 2.

XII. Claim 77 drawn to **a Kit** comprising **an RNA molecule** comprising 15 to 25 nucleotide pairs, comprising a nucleotide sequence corresponding to a partial sequence of a nucleotide sequence from positions 436 to 1413 of SEQ ID NO: 2 and a pharmaceutical composition.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

> "If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

> "If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-XII appears to be that they all relate to methods and therapeutic compositions comprising a polypeptide fragment of SEQ ID NO: 1, and nucleic acid sequences (DNA and RNA) of partial homology with SEQ ID NO:2 . However, prior art has taught novel HKID-1 polypeptides, proteins, and nucleic acid molecules including the amino acid sequence of SEQ ID NO. 2 having partial sequence homology with the amino acid sequence of SEQ ID NO: 1 of the invention (Kapeller et al., US Patent 6,383,791, Date of patent May 7, 2002). Therefore, the technical feature linking the invention of groups I-XII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions of Groups I-XII are drawn to materially different and distinct inventive concepts, having different chemical structures, physical properties and biological functions. For examples, inventions of Group V drawn to a polynucleotide (e.g, a nucleotide sequence of SEQ ID NO: 2, a polynucleotide encoding an amino acid sequence comprising the amino acid sequence of SEQ ID NO:1) are structurally and functionally different from inventions of Group I, drawn a protein of SEQ ID NO:1 and homologous sequences as the result of comprising either polynucleotides or polypeptides which require separate searches; they are not obvious variants and deemed patentably distinct for the following reasons: polynucleotides, which are composed of purine and pyrimidine units and polypeptides/proteins, which are composed of amino acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Moreover, because of the degeneracy of the genetic code, different nucleotide sequences can encode the same polypeptide sequence. Hence, the information provided by a polynucleotide of Group V can be used to make a materially different polypeptide than that of Group I. Moreover, inventions of Group III drawn to antibodies include unique technical features that are not shared by the inventions of Groups I or V. For example, antibodies are proteins made of two large heavy chains H and two small light chains L, which are produced by B cells. Furthermore, inventions of Groups II, VI, VIII, and XI are drawn to methods comprising unique technical features that

are not shared by the inventions of Groups I, III and V, for example, inventions of Group II is drawn to a method for production of antibodies, inventions of Group VI is drawn to a method for production for the production of a polypeptide comprising culturing a host cell transformed with a vector comprising a polynucleotide, inventions of Group VIII drawn to a method for detecting a polynucleotide requires using a PCR primer and inventions of Group XI, drawn to a method for the production of a knockout cell, requires introducing an RNA molecule into a cell expressing a protein specific to human liver cancer. Moreover, inventions of Groups IV, IX and XII drawn to kits comprise unique technical features that are not shared by the inventions of Groups I, II, III, V, VI, VIII and XI. For example, the kit of Group IV comprises one or more antibodies elicited against the amino acid sequence of SEQ ID NO:1, the kit of Group IX comprises PCR primers and the kit of Group XII comprises an RNA molecules comprising 15 to 25 nucleotide pairs .

The claims in Groups I-XII are drawn to distinct products and methods that utilize distinct steps, requiring non-coextensive search and examination. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-XII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

Species restriction

Should Group **I, II, III, IV, V, VI or X** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

1) at least an amino acid residue at position 39, 85, 296, or 300 from the N-terminus is Ala,

an amino acid residue at position 86 or 310 is Thr,

an amino acid residue at position 163 or 303 is Ser,

an amino acid residue at position 195 or 257 is Leu,

an amino acid residue at position 271 is Arg,

an amino acid residue at position 297 is Asp,

an amino acid residue at position 299 is Gly,

an amino acid residue at position 313 is Pro,

an amino acid residue at position 316 is Val, of the amino acid sequence of **SEQ ID NO: 1**,

a nucleotide sequence from positions 436 to 1413 **of SEQ ID NO: 2**, and

the nucleotide sequence of **SEQ ID NO: 10**, as recited in claims 38, 42, 43, 44, 48, 52, 64, 71 and 72

The species are independent or distinct because there are nucleotide sequences and proteins sequences that involve nucleic acid molecules which are each distinct nucleic acid coding sequences encoding specific and unique polypeptides. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature of a nucleotide sequence coding for a polypeptide, linking the members does not constitute a special technical feature as defined by PCT Rule 13.2, particularly since

each of the each nucleic acid does not overlap in scope with the others, are not obvious variants, and have materially different functions, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 38, 48, 60 and 64 are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, Ph.D.
Examiner, Art Unit 1633